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(54) **METHOD AND APPARATUS FOR EXTERNAL HEART STABILIZATION**

VERFAHREN UND GERÄT FÜR DIE EXTERNE HERZSTABILISIERUNG

METHODE ET APPAREIL POUR STABILISATION EXTERNE DU COEUR

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to devices for treating dilatation of the valves at the base of the heart by external stabilization of the base of the heart, which subtend the atrio-ventricular valves of the heart.

BACKGROUND OF THE ART

[0002] Dilatation of the base of the heart occurs with various diseases of the heart and often is a causative mechanism of heart failure. In some instances, depending on the cause, the dilatation may be localized to one portion of the base of the heart (e.g., mitral insufficiency as a consequence of a heart attack affecting the inferior and basal wall of the left ventricle of the heart), thereby affecting the valve in that region. In other cases, such as cardiomyopathy, the condition may be global affecting more of the heart and its base, causing leakage of particularly the mitral and tricuspid valves. Other conditions exist where the mitral valve structure is abnormal, predisposing to leakage and progressive dilatation of the valve annulus (area of valve attachment to the heart). This reduces the amount of blood being pumped out by the ventricles of the heart, thereby impairing cardiac function further.

[0003] In patients with heart failure and severe mitral insufficiency, good results have been achieved by aggressively repairing mitral and/or tricuspid valves directly, which requires open-heart surgery (Bolling, *et al.*). The mitral valve annulus is reinforced internally by a variety of prosthetic rings (Duran Ring, Medtronic Inc) or bands (Cosgrove-Edwards Annuloplasty Band, Edwards Lifesciences Inc). The present paradigm of mitral valve reconstruction is therefore repair from inside the heart, with the annulus being buttressed or reinforced by the implantation of a prosthetic band or ring. Since this is major open-heart surgery with intra-cavitary reconstruction, there is the attendant risk of complications and death associated with mitral valve surgery. Another approach has been to replace the mitral valve, which while addressing the problem, also requires open-heart surgery and involves implantation of a bulky artificial, prosthetic valve with all its consequences. Because every decision to perform major surgery requires some risk vs. benefit consideration, patients get referred for risky surgery only when they are significantly symptomatic or their mitral valve is leaking severely.

[0004] In contrast to the more invasive approaches discussed above, in specific instances of inferior left ventricular wall scarring causing mitral regurgitation, Levine and co-workers have suggested localized pressure or support of the bulging scar of the inferior wall of the heart from the outside.

[0005] Another less invasive approach to preventing global heart dilation is ventricular containment with a custom made polyester mesh, or cardiac support device (U.S. Patent Nos. 6077218 and 6123662). These devices are designed to provide a passive constraint around both ventricles of the heart, and constrain diastolic expansion of the heart. Other devices include ventricular assist devices that provide cardiac assistance during systole and dynamic ventricular reduction devices that actively reduce the size of the heart. However, this technique does not specifically address valve leakage using a device that reinforces the base of the heart in all phases of the cardiac cycle.

[0006] US Patent No 6,123,662 describes devices ("jackets") for treating congestive heart disease and related cardiac complications such as valvular disorders. The jacket is made of biologically compatible material, and has a shape and size that allows it be slipped over the apex of the heart. The jacket has a width that this sufficient for it to surround both the valvular annulus of the heart and at least the ventricular lower extremities of the heart. Figure 4A therein illustrates an "open-ended" embodiment in which the apex of the heart protrudes slightly. The dimension, L, in Figure 4, is relatively large, in order to be sure that the device extends beyond the lower ventricular extremities (LE) and encompasses the ventricle chambers.

[0007] US Patent No 6,264,602 describes a range of devices for reducing mechanical heart wall muscle stress (and in particular, the left ventricle) that are useful in the treatment of heart failure. The devices ("splints") change heart chamber geometry in order to lower heart wall stress, and may be used in combination with "wraps" that do not change chamber geometry. Most of the devices are "penetrating" (and are not "external") and include a transventricular member. See, for example, Figures 1 and 2. Many of the devices do not completely circle the base of the heart. See, for example, Figure 10. A few of the devices are non-penetrating splints with complex (non-strip) configurations. See, for examples, Figures 17 and 26. Figure 30 shows a wide wrap (200) that is substantially similar to the wrap 11 shown in Figures 1 and 2, but extends vertically a greater distance along the heart than wrap 11, and is not shown with a transventricular splint.

[0008] US Patent No 6,126,590 describes "cardiac reinforcement devices" which constrain cardiac expansion (limit the outward expansion of the heart wall), beyond a predetermined limit, during diastolic expansion (chamber filling) of the heart. This is apparently in contrast to earlier devices that provide cardiac reinforcement during systole (contraction). The devices are useful in the treatment of cardiac diseases associated with atrial or ventricular dilation, such as cardiomyopathies where abnormal dilation of one or more chambers of the heart is a component of the disease. The devices may also be used to reduce the diastolic volume of the heart. In some cases, the device is shaped as a jacket that surrounds the epicardial surface of the heart and circumferentially constrains cardiac expansion. The apex of the jacket

can have an opening through which the apex of the heart protrudes. Figures 4 and 5 illustrate an open-ended jacket in which the apex of the heart protrudes from the apical end of the jacket. The jacket includes a circumferential attachment device (element 43) that secures the jacket near the base of the heart (element 44).

[0009] Accordingly, there is a need to provide a less invasive, simple technique of repairing, reinforcing, reducing or stabilizing the base of the heart and its underlying valves (mitral and tricuspid valves) from the outside.

DISCLOSURE OF THE INVENTION

[0010] The present invention addresses the problems discussed above by providing a device for the treatment of certain heart disorders, in particular mitral and/or tricuspid valve insufficiency. The device aims to reduce the size of the base of the heart that contains these valvular structures. In addition, the present invention can be used to address progressive dilatation of any localized area of the heart, such as the atrial or ventricular myocardium, or the cardiac base. It does so by providing external reinforcement or remodeling of the cardiac base. As used herein, the surgical procedure for implanting the device is referred to as basal annuloplasty of the cardia externally ("BACE") and the device is referred to as the external cardiac basal annuloplasty system ("ECBAS") or BASE System.

[0011] In one use, a customized or specially constructed biocompatible strip is implanted along the base of the heart at the level of the atrio-ventricular groove. The strip or mesh is between 2 and 5 cm wide and is secured by 2 rows of clips or sutures, one on the atrial side and the other on the ventricular side of the atrio-ventricular groove. Specific care is taken to avoid injury to the circumflex and right coronary arteries and the coronary sinus. This procedure may be performed either as a stand-alone procedure or as an adjunct to other cardiac surgery. Additionally, it may be performed with or without the aid of cardio-pulmonary bypass.

[0012] Another embodiment is a device or strip, which once implanted at a certain size, can be tightened over time either by inflation of an attached chamber or programmed to return to a pre-formed size (based on elasticity or pre-existing memory) of the material used.

[0013] Another embodiment of this device, while externally stabilizing the base of the heart, also provides a localized increase in contraction along any segment of the base to improve contractile function. This may be accomplished by the aid of contractile metal or modified muscle or other cells.

[0014] Variations of the device include a complete stabilization of the base of the heart, or a partial stabilization around the expansile portions of the mitral and tricuspid valves by a biocompatible strip.

[0015] Another variation seeks to use ports along the device that will facilitate delivery of specialized drugs, gene therapeutic agents, growth factors, etc.

[0016] A specific variation incorporates the use of epicardial bi-ventricular pacing electrodes implanted along with the BACE-Sys, where multi-site pacing might be indicated.

[0017] Also described herein is a method of implantation, which may be through a conventional full median sternotomy with the strip being secured by sutures, or a minimally invasive approach whereby the device/strip may be implanted by a specialized implantation system using adhesives, self-firing clips, sutures, etc.

[0018] Another modification of this technique is the local application of prosthetic material to stabilize scars of the heart to prevent their expansion (local ventricular stabilization).

[0019] Thus, a first aspect of the present invention is a device, suitable for use as an external stabilizer of a heart base, comprising:

> a biocompatible, implantable material in a strip configuration comprising a top edge, a bottom edge, and a center portion;

wherein:

> either: the distance between the outside of the top edge and the outside of the bottom edge is between 2 and 5 cm;
> or: the width of the device is less than or equal to 1/2 X, wherein X is the distance between the base and the bottom of the apex of the heart;

which is adapted for external application to the heart base,
and which in use:

> completely circles the base of the heart;
> subtends the atrio-ventricular valves of the heart; and
> decreases, and/or prevents increases in, the dimensions of the base of the heart beyond a predetermined size in all phases of the cardiac cycle.

[0020] In one embodiment, the distance between the outside of the top edge and the outside of the bottom edge is between 2 and 5 cm.

[0021] In one embodiment, the width of the device is less than or equal to 1/2 X, wherein X is the distance between the base and the bottom of the apex of the heart.

[0022] In one embodiment, the device, in use, is placed epicardially around the base of the heart.

[0023] In one embodiment, the device, in use, is placed in the atrio-ventricular groove.

[0024] In one embodiment, the center portion further comprises an open mesh.

[0025] In one embodiment, the open mesh further comprises opening sizes between 2 mm to 2 cm, when measured along the longest axis.

[0026] In one embodiment, the top and bottom edge further comprise a metal.

[0027] In one embodiment, the center portion further comprises a polyester mesh.

[0028] In one embodiment, the device further comprises attachment means.

[0029] In one embodiment, the device further comprises attachment members.

[0030] In one embodiment, the attachment members further comprise eyelets.

[0031] Another aspect of the present invention pertains to a device of the first aspect for use in method of treatment of the human or animal body.

[0032] Another aspect of the present invention pertains to a device of the first aspect for use in the treatment of dilatation of the valves at the base of the heart.

[0033] Another aspect of the present invention pertains to a device of the first aspect for use in the treatment of mitral and/or tricuspid valve insufficiency.

[0034] Another aspect of the present invention pertains to a device of the first aspect for use in the treatment of regurgitation of the mitral and tricuspid valves.

[0035] Another aspect of the present invention pertains to a device of the first aspect for use in the treatment of mitral regurgitation.

[0036] Another aspect of the present invention pertains to a device of the first aspect for use in the treatment of progressive dilatation of the cardiac base.

[0037] Another aspect of the present invention pertains to a device of the first aspect for prophylactic use to prevent further cardiac basal dilation or expansion.

[0038] Another aspect of the present invention pertains to a device of the first aspect for use in treatment to reduce the size of the dilated base of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039]

Figure 1 depicts a cross-section of the heart, showing the approximate location of a representative embodiment of the device of the present invention by dashed lines.

Figure 2 depicts a cross-section of the base of the heart between the dotted lines depicted in Figure 1.

Figure 3 depicts a cross-sectional schematic diagram of the base of the heart. As depicted therein, PV=pulmonary valve, MV=mitral valve, AV=aortic valve and TV=tricuspid valve.

Figure 4 depicts a traditional method of repairing MV and TV with bands inside the heart.

Figure 5 depicts basal angioplasty of the cardia externally.

Figure 6 depicts a representative embodiment of the device of the present invention.

Figure 7 depicts a schematic drawing of a heart with a representative device of the present invention in place.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0040] The present invention relates to external support of the base of the heart. The support functions to decrease, and/or prevent increases in, the dimensions of the base, and in particular the atrio-ventricular junction, beyond a pre-determined size. The device is designed to reduce the size of the cardiac base in a manner similar to an internal annuloplasty band or ring.

[0041] This invention is particularly suited for use in the treatment of regurgitation of the mitral and tricuspid valves. The device may also be used prophylactically in heart failure surgery to prevent further cardiac basal dilatation or expansion even if the underlying mitral and tricuspid valves are competent. The device may be used in moderate or advanced heart failure to prevent progression of basal dilatation or reduce the size of the dilated base.

[0042] As used herein, "cardiac base" refers to the junction between the atrial and ventricular chambers of the heart, also known as the atrio-ventricular junction marked externally by the atrio-ventricular groove. This is easily identified in the change of appearance of the cardiac muscle and also the presence of arteries and veins.

[0043] The heart is enclosed within a double walled sac known as the pericardium. The inner layer of the pericardial sac is the visceral pericardium or epicardium. The outer layer of the pericardial sac is the parietal pericardium. The term "endocardial surface" refers to the inner walls of the heart. The term "epicardial surface" refers to the outer walls of the heart.

[0044] The mitral and tricuspid valves sit at the base of the heart and prevent blood from leaking back into the atria or collecting chambers. See Figure 1. Mitral regurgitation is a condition whereby blood leaks back through the mitral valve into the left atrium. Over time, this creates a damming of blood in the lungs causing symptoms of shortness of breath. The left heart particularly the left ventricle has to pump a greater volume of blood as a result causing greater strain on this chamber.

[0045] Dilatation of the mitral annulus occurs maximally in the posterior portion of the annulus, which is not supported by the cardiac fibro-skeleton. Figure 2 is an anatomic diagram of the base of the heart, showing the valves and the structures in contact with them. Figure 3 is a schematic representation of the valves at the cardiac base.

[0046] Mitral valve repair or replacement at present is always performed from inside the heart with the aid of cardiop-ulmonary bypass. Rings are implanted along the inner surfaces of the entire or expansile portions of the mitral and tricuspid annuli (Figure 4). Alternatively, when mitral valve malfunction is severe, replacement of the valve with a prosthetic valve may be indicated.

Overview

[0047] The basal ventricular stabilization of the present invention works by using a prosthetic material such as polyester mesh anchored or sutured to the base of the heart at the level of the atrio-ventricular groove. This serves to stabilize the mitral and tricuspid annuli from the outside (Figure 5). This technique reduces the complexity of the procedure and minimizes the invasive nature and complications from work on the valve. This technique is of particular benefit in patients that have morphologically normal valves with annular dilatation. The device can be applied and anchored to the cardiac base, with the heart beating, without the aid of cardio-pulmonary bypass.

[0048] Many patients with moderate degrees of mitral regurgitation are not treated surgically, because the risks of surgery outweigh the potential benefits in this group of patients. However, patients with conditions such as chronic heart failure tend to get very symptomatic even with moderate degrees of mitral regurgitation. These groups of patients would benefit from the less invasive procedures. Thus, the potential of this technique in treating mitral regurgitation as a minimally invasive procedure has great appeal as the population ages and more patients manifest with symptoms of heart failure. It also can be applied en passant in patients undergoing coronary artery surgery without the aid of a heart-lung machine.

Device Parameters

[0049] The device of the present invention can be constructed of any suitable implantable material. Examples of such materials are well known in the art and include, e.g., synthetic polymers such as polyester, polytetrafluoroethylene, polypropylene, teflon felt, etc., as well as metallic materials such as stainless steel. Such metals may provide "memory", such that they return to a specific shape after deformation, and in this manner provide an element of dynamic contraction. In yet another embodiment, the device may be constructed either partially or completely of natural materials, such as polyglycolic acid or compressed and/or crosslinked collagen, which may or may not be reinforced with synthetic polymers or other means. Any material is suitable that is biocompatible, implantible, and preferably has a compliance that is lower than the heart wall. Other variations include incorporation of elastic material or elastin ingrowth into the biomaterial.

[0050] As shown in Figure 6, the device is in a "strip" configuration and comprised of two edge members and a center portion, each of which may be constructed by the same or different material. In one embodiment (not shown), there is no distinction between the edge members and the center portion and the device is completely uniform from top to bottom.

[0051] The center portion of the device may be in the form of a solid single or multilayer sheet, but is preferably of an open mesh, porous or woven design, such that the exterior of the heart is not completely covered and therefore remains exposed to the surrounding tissue. The size of the openings in the mesh can vary, for example from 2 mm to 2 cm, and can take any shape, such as circular, square, octagonal, triangular, or irregular. In a preferred embodiment, the center portion of the device is a mesh as depicted in Figure 6.

[0052] The center portion may also be adapted for the delivery of various therapeutic agents, such as growth factors or plasma proteins. In addition, it may be adapted to facilitate cellular growth, which in turn may facilitate anchorage of the device.

[0053] The device is designed to completely circle the base of the heart.

[0054] The biomaterial from which the device is constructed may also be radiolucent , radio-opaque or have radio-opaque markers at pre-set intervals to monitor the movement of the cardiac base in real-time using fluoroscopy and to facilitate implantation.

[0055] The device may be completely rigid prior to implantation, or may have regions of varying rigidity. However, it is important that the device is sufficiently flexible to move with the expansion and contraction of the heart without impairing its function. It should, however, be designed to prevent expansion of the cardiac base during diastolic filling of the heart to a predetermined size. Since the size expansion parameters of a beating heart are well known, this can be accomplished by testing the device in vitro by applying forces that mimic heart expansion.

[0056] The edges of the device, which are depicted in Figure 6 having securing eyelets attached thereto, may be constructed of a more rigid material, such as carbon fiber tubing. In addition, means of making the device, or portions thereof, such as one or both edges and/or the center portion, more or less rigid post-implantation are also within the present invention. For example, the center portion may be constructed of a partially biodegradable material and may become more flexible after implantation when the biodegradable material is hydrolyzed by the surrounding tissues and fluids. Alternatively, the edges may be provided with means for making them more rigid or flaccid prior to implantation, such as by inflating/deflating closed chambers. Many alternate means for adjusting the rigidity/flexibility of the device, or portions thereof, would be easily adapted from other mechanisms known in the surgical arts.

Device Attachment

[0057] The device may be attached to the outside of the base of the heart by any known method. For example, attachment may be biological, chemical or mechanical. Biological attachment may be brought about by the interaction of the device with the surrounding tissues and cells, and can be promoted by providing appropriate enhancers of tissue growth. Alternatively, chemical attachment may be provided by supplying a mechanism for chemical attachment of the device, or portions thereof, to the external surface of the heart. In yet another embodiment, the rigidity and tightness of the device around the heart may provide for sufficient mechanical attachment due to the forces of the heart against the device without the need for other means of attachment. In a preferred embodiment, however, as depicted in Figure 6, the device further comprises attachment members, such as the eyelets shown therein. Specific anchor points or loops made of any biocompatible and implantable material may be attached to the edges or to the center portion or both to facilitate anchoring. Suitable materials include, inter alia, polyester, polypropylene or complex polymers. Alternative attachment members may comprise suture materials, protrusions that serve as sites for suturing or stapling, as well as other structural members that facilitate attachment to the surface of the heart.

Device Size

[0058] Although the size of the device depends on the purpose for which it is being implanted, it is contemplated that the device will be wide enough (measured from the outside of the first or top edge, i.e. the base edge, to the outside of the second or bottom edge, i.e. the apex edge) to provide efficient support to the atrio-ventricular grove. Accordingly, the device is between 2 and 5 centimeters wide.

[0059] The distance between the base and the bottom of the apex of the heart can be expressed as distance "X". Because the focus of the device of the present invention is base stabilization; it is generally preferred that the width of the device additionally be less than or equal to 1/2 X, and be adapted for placement around the top half of the distance X, i.e. closer to the base than the bottom of the apex.

Implantation

[0060] The ECBAS or BASE system may be implanted through a conventional midline total sternotomy, sub maximal sternotomy or partial upper or lower sternotomy. Alternatively, the device may be implanted through a thoracotomy incision, or a Video Assisted Thoracoscopic (VAT) approach using small incisions. The BASE system can also be implanted by a sub-costal incision as in the Sub-Costal Hand-Assisted Cardiac Surgery (SHACS). Additionally, the BASE system may be implanted with sutures onto the epicardium or clips, staples, or adhesive material that can secure the device on the heart accurately. The device may also be implanted using robotic placement of the device along the posterior aspects of the base of the heart.

[0061] The method of implantation and the adequacy of the external annuloplasty can be dynamically assessed by intra-operative trans-esophageal echocardiography, epicardial echocardiography or trans-thoracic echocardiography. The size of the device is assessed based on external circumference measurements of the cardiac base in the fully loaded beating heart state.

Versions of the BACE systems

A. BACE with pace

[0062] In another embodiment, the ECBAS has attached close to or within it epicardial steroid eluting pacing wires that can facilitate multi-site ventricular pacing for heart failure.

B. Dynamic BACE

[0063] In this embodiment, the device has fluid filled chambers that may be inflated gradually over time, to gradually reduce the size of the cardiac base. These chambers may also effect passive transfer of energy to facilitate diastolic and systolic support with a closed pericardium.

C. Smart & dynamic BACE

[0064] In this embodiment, the bio-material would have the capability to shrink to a pre-formed size over a period of time, based on the memory of the material or some other programmable characteristic. This would achieve controlled reduction over a period of time of the base of the heart.

D. Cellular BACE

[0065] In this embodiment, the bio-material uses available matrix technology, and seeding of appropriate cells to provide dynamic reduction and assistance to the cardiac base.

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[0066]

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EXAMPLES

Example 1: BACE procedure

[0067] **Abstract:** Over a 12 month period, ten patients underwent Basal Annuloplasty of the Cardia Externally (BACE), to correct moderate mitral regurgitation. This technique involves securing a specially constructed polyester mesh like device to the epicardial surface of the cardiac base, at the level of the atrio-ventricular groove. These procedures were performed in conjunction with coronary artery surgery in all patients. All patients demonstrated a dramatic improvement in functional status, quality of life, mitral regurgitation and function of the heart. BACE can be performed safely with expectation of a good clinical outcome as an adjunct to conventional heart surgery.

Clinical approach and experience:

[0068] Careful pre-operative screening included radionuclide ventriculography to document left ventricular ejection fraction, a detailed trans-thoracic echocardiogram, a coronary angiogram, and in most cases a stress thallium and/or a

Positron Emission Tomographic Scan looking for myocardial viability. The functional status of the patients were carefully documented by a heart failure cardiologist and nurse.

Ten patients who were undergoing conventional cardiac surgery, usually in the setting of poor cardiac function with moderate mitral regurgitation, were enrolled. All of these patients had coronary artery bypass surgery. All of them had at least moderate mitral regurgitation pre-operatively and intra-operatively (confirmed by trans-esophageal echocardiography). All of these patients had the Basal Annuloplasty of the Cardia Externally (BACE) performed with a polyester mesh constructed intra-operatively, based on the measured circumference of the cardiac base.

Surgical Technique:

[0069] The circumference of the base of the heart at the level of the atrio-ventricular groove was measured before the patient was connected to cardio-pulmonary bypass (CPB). Based on these measurements, a strip of polyester mesh measuring 2.5 to 3 cm in width was cut to size and fashioned, such that its length would be less than the basal circumference by about 2.5 to 4.5 cms. Once the patient was connected to cardiopulmonary bypass, the coronary artery bypass grafts were performed. Left ventricular reconstruction was performed when indicated.

The constructed BACE mesh was anchored posteriorly at the level of the atrio-ventricular groove, on atrial and ventricular sides with combination of 4/0 Ticron™ sutures and hernia staples, which were placed about 1.5 to 2 cm apart. The mesh was secured laterally as well. Final assessment of the tension and the securing of the BACE system was performed with the patient weaned off cardio-pulmonary bypass with the heart filled to pre CPB levels. The mesh was then tightened and secured just as the mitral regurgitation was abolished on trans-esophageal echocardiographic monitoring.

Post-operative Course:

[0070] All these patients had trivial to mild mitral regurgitation at the completion of the procedure. At follow-up, 3, 6 and 12 months post-operatively, all of these patients demonstrated improved cardiac function (as measured by left ventricular ejection fraction), improved functional status and quality of life, and were able to maintain their improvement in the degree of mitral regurgitation. Radionuclide ventriculography was used to determine the left ventricular ejection fraction pre- and post-operatively. Compared to a preoperative value of 25 $\pm$ 3.1% (n=8), the ejection fractions improved to 40 $\pm$ 14.2% and 39.3 $\pm$ 5.7% after 3 and 6 months post-operatively, respectively ($p<5$). Likewise, the New York Heart Association (NYHA) classification was used as an index of functional heart status. Compared to a pre-operative value of 3.11 $\pm$ 0.33 (n=8), the NYHA improved to 1.17 $\pm$ 0.41 after 3 months post-operatively ($p<5$). Mitral regurgitation (graded 1 to 4) was also observed to improve dramatically from 3.01 pre-operatively to 0.1 post-operatively after 6 months ($p<5$). In addition, there was improvement in tricuspid regurgitation as well.

[0071] **Discussion**:Dilatation of the cardiac base often accompanies heart failure. This may be a secondary development due to volume overload and increased left ventricular wall stress. In cases of mitral or tricuspid valvular heart disease, annular dilatation occurs along with decompensation of the regurgitant lesions. Severe annular dilatation accompanies severe regurgitation. However, significant basal dilatation may co-exist with moderate or moderately severe atrioventricular valve regurgitation. Since repair of these conditions requires intra-cavitary repair of the affected annulus, the majority of surgeons tend to leave moderate and moderately severe mitral and/or tricuspid regurgitation alone. Using the methods and apparatuses described herein, these conditions can be corrected from the outside of the heart. Furthermore, the correction can be tailored under trans-esophageal echocardiographic guidance. This avoids intra-cavitary manipulation. In selected cases, this procedure could be performed with the heart beating also and without using the heart-lung machine, making it an "off-pump" procedure.

Example 2: Comparative and Long Range Studies using BACE Procedure

[0072] Twelve patients were treated with the BACE procedure as described in Example 1. All of the patients had pre- and post-operative studies at 3, 6, 12 and 18 months, including echocardiography and radionuclide ventriculography to look at cardiac function, amount of mitral regurgitation and the size of the hearts. All twelve patients were very symptomatic, with the majority in New York Heart Association (NYHA) class III status. The mean left ventricular ejection fraction (LVEF) was 25% preoperatively and all patients had moderate mitral regurgitation.

[0073] The BACE procedure was performed on cardio-pulmonary bypass with the heart decompressed. The procedure took approximately 15 minutes of extra bypass time and about 5 minutes of extra cross-clamp time.

[0074] The results are shown below in Table 1. As shown, the BACE procedure dramatically improved cardiac function and was at least equivalent to mitral valve repair eighteen months post-operatively.

Table 1

BACE Procedure Results				
	Pre-Op	6 months	12 months	18 months
NYHA Functional Status	3.11	1.14	1.2	----
Left Ventricular Ejection Fraction (%)	25.0	39.3	43.1	44.5
Degree of Mitral Regurgitation - BACE Patients	2.8	-----	-----	.3
Degree of Mitral Regurgitation - Mitral Valve Replacement Patients	3.7	-----	-----	.7

Claims

1. A device, suitable for use as an external stabilizer of a heart base, comprising:

a biocompatible, implantable material in a strip configuration comprising a top edge, a bottom edge, and a center portion;

wherein:

either: the distance between the outside of the top edge and the outside of the bottom edge is between 2 and 5 cm;
or: the width of the device is less than or equal to 1/2 X, wherein X is the distance between the base and the bottom of the apex of the heart;

which is adapted for external application to the heart base,
and which in use:

completely circles the base of the heart;
subtends the atrio-ventricular valves of the heart; and
decreases, and/or prevents increases in, the dimensions of the base of the heart beyond a predetermined size in all phases of the cardiac cycle.

2. A device according to claim 1, wherein the distance between the outside of the top edge and the outside of the bottom edge is between 2 and 5 cm.

3. A device according to claim 1, wherein the width of the device is less than or equal to 1/2 X, wherein X is the distance between the base and the bottom of the apex of the heart.

4. A device according to any one of claims 1 to 3 which, in use, is placed epicardially around the base of the heart.

5. A device according to claim 4 which, in use, is placed in the atrio-ventricular groove.

6. A device according to any one of claims 1 to 5, wherein the center portion further comprises an open mesh.

7. A device according to claim 6, wherein the open mesh further comprises opening sizes between 2 mm to 2 cm, when measured along the longest axis.

8. A device according to any one of claims 1 to 7, wherein the top and bottom edge further comprise a metal.

9. A device according to any one of claims 1 to 8, wherein the center portion further comprises a polyester mesh.

10. A device according to any one of claims 1 to 9, further comprising attachment means.

11. A device according to any one of claims 1 to 9, further comprising attachment members.

12. A device according to claim 11, wherein the attachment members further comprise eyelets.

13. A device according to any one of claims 1 to 12 for use in method of treatment of the human or animal body.

14. A device according to any one of claims 1 to 12 for use in the treatment of dilatation of the valves at the base of the heart.

15. A device according to any one of claims 1 to 12 for use in the treatment of mitral and/or tricuspid valve insufficiency.

16. A device according to any one of claims 1 to 12 for use in the treatment of regurgitation of the mitral and tricuspid valves.

17. A device according to any one of claims 1 to 12 for use in the treatment of mitral regurgitation.

18. A device according to any one of claims 1 to 12 for use in the treatment of progressive dilatation of the cardiac base.

19. A device according to any one of claims 1 to 12 for prophylactic use to prevent further cardiac basal dilation or expansion.

20. A device according to any one of claims 1 to 12 for use in treatment to reduce the size of the dilated base of the heart.

Patentansprüche

1. Vorrichtung, geeignet zur Verwendung als ein äußerer Stabilisator einer Herzbasis, welche umfasst:

ein biokompatibles, implantierbares Material in einer Streifenanordnung, welche einen oberen Rand, einen unteren Rand und einen Mittelteil umfasst;

wobei:

entweder: der Abstand zwischen der Außenseite des oberen Randes und der Außenseite des unteren Randes zwischen 2 und 5 cm ist;
oder: die Breite der Vorrichtung kleiner oder gleich ½ X ist, wobei X der Abstand zwischen der Basis und dem unteren Ende des Apex des Herzens ist;

die zur äußeren Anwendung an der Herzbasis ausgelegt ist,
und welche bei Verwendung:

die Basis des Herzens vollständig umgibt;
den atrioventrikulären Klappen des Herzens gegenüberliegt; und
die Ausdehnungen der Basis des Herzens über eine vorbestimmte Größe hinaus in allen Phasen des Herzzyklus verringert, und/oder Zunahmen der Ausdehnungen der Basis des Herzens über eine vorbestimmte Größe hinaus in allen Phasen des Herzzyklus verhindert.

2. Vorrichtung gemäß Anspruch 1, wobei der Abstand zwischen der Außenseite des oberen Randes und der Außenseite des unteren Randes zwischen 2 und 5 cm ist.

3. Vorrichtung gemäß Anspruch 1, wobei die Breite der Vorrichtung kleiner oder gleich ½ X ist, wobei X der Abstand zwischen der Basis und dem unteren Ende des Apex des Herzens ist.

4. Vorrichtung gemäß einem der Ansprüche 1 bis 3, welche bei Verwendung epikardial um die Basis des Herzens platziert ist.

5. Vorrichtung gemäß Anspruch 4, welche bei Verwendung in der Herzkranzfurche platziert ist.

6. Vorrichtung gemäß einem der Ansprüche 1 bis 5, wobei der Mittelteil ferner ein offenes Gitter umfasst.

7. Vorrichtung gemäß Anspruch 6, wobei das offene Gitter ferner Öffnungsgrößen zwischen 2 mm bis 2 cm umfasst, wenn entlang der längsten Achse gemessen wird.

8. Vorrichtung gemäß einem der Ansprüche 1 bis 7, wobei der obere und untere Rand ferner ein Metall umfassen.

9. Vorrichtung gemäß einem der Ansprüche 1 bis 8, wobei der Mittelteil ferner ein Polyestergitter umfasst.

10. Vorrichtung gemäß einem der Ansprüche 1 bis 9, welche ferner Befestigungsmittel umfasst.

11. Vorrichtung gemäß einem der Ansprüche 1 bis 9, welche ferner Befestigungselemente umfasst.

12. Vorrichtung gemäß Anspruch 11, wobei die Befestigungselemente ferner Ösen umfassen.

13. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung in einem Behandlungsverfahren des menschlichen oder tierischen Körpers.

14. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei der Behandlung von Klappendilatation an der Basis des Herzens.

15. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei der Behandlung Mitral- und/oder Trikuspidalklappeninsuffizienz.

16. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei der Behandlung von Mitral- und Trikuspidalklappenregurgitation.

17. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei der Behandlung von Mitralregurgitation.

18. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei der Behandlung einer progressiven Dilatation der Herzbasis.

19. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur prophylaktischen Verwendung, um eine weitere basale Herzdilatation oder -expansion zu verhindern.

20. Vorrichtung gemäß einem der Ansprüche 1 bis 12 zur Verwendung bei einer Behandlung, um die Größe der dilatierten Basis des Herzens zu reduzieren.

Revendications

1. Dispositif, approprié pour être utilisé en tant que stabilisateur externe d'une base cardiaque, comprenant :

un matériau implantable biocompatible se présentant dans la configuration d'une bande comprenant un bord supérieur, un bord inférieur et une partie centrale ;

dans lequel :

soit : la distance entre l'extérieur du bord supérieur et l'extérieur du bord inférieur est comprise entre 2 et 5 cm ;
soit : la largeur du dispositif est inférieure ou égale à 1/2 X, où X est la distance entre la base et le fond du sommet du coeur ;
qui est adapté pour l'application externe sur la base du coeur,

et qui, à en utilisation :

encercle complètement la base du coeur ;
sous-tend les valves auriculo-ventriculaires du coeur ; et
diminue et/ou empêche les augmentations de dimensions de la base du coeur au-delà d'une taille prédéterminée dans toutes les phases du cycle cardiaque.

2. Procédé selon la revendication 1, dans lequel la distance entre l'extérieur du bord supérieur et l'extérieur du bord inférieur est comprise entre 2 et 5 cm.

3. Dispositif selon la revendication 1, dans lequel la largeur du dispositif est inférieure ou égale à 1/2 X, où X est la distance entre la base et le fond du sommet du coeur.

4. Dispositif selon l'une quelconque des revendications 1 à 3 qui, en utilisation, est placé de manière épicardique autour de la base du coeur.

5. Dispositif selon la revendication 4 qui, en utilisation, est placé dans un sillon auriculo-ventriculaire.

6. Dispositif selon l'une quelconque des revendications 1 à 5, dans lequel la partie centrale comprend en outre une maille ouverte.

7. Dispositif selon la revendication 6, dans lequel la maille ouverte comprend des tailles d'ouverture comprises entre 2 mm et 2 cm, lorsqu'elles sont mesurées le long de l'axe le plus long.

8. Dispositif selon l'une quelconque des revendications 1 à 7, dans lequel les bords supérieur et inférieur comprennent en outre un métal.

9. Dispositif selon l'une quelconque des revendications 1 à 8, dans lequel la partie centrale comprend en outre une maille en polyester.

10. Dispositif selon l'une quelconque des revendications 1 à 9, comprenant en outre des moyens de fixation.

11. Dispositif selon l'une quelconque des revendications 1 à 9, comprenant en outre des éléments de fixation.

12. Dispositif selon la revendication 11, dans lequel les éléments de fixation comprennent en outre des oeillets.

13. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé dans un procédé de traitement du corps humain ou animal.

14. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé pour le traitement de la dilatation des valves à la base du coeur.

15. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé pour le traitement de l'insuffisance de la valve mitrale et/ ou tricuspide.

16. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé pour le traitement de la régurgitation des valves mitrale et tricuspide.

17. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé pour le traitement de la régurgitation mitrale.

18. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé pour le traitement de la dilatation progressive de la base cardiaque.

19. Dispositif selon l'une quelconque des revendications 1 à 12, pour l'utilisation prophylactique afin d'empêcher la dilatation ou l'expansion supplémentaire de la base cardiaque.

20. Dispositif selon l'une quelconque des revendications 1 à 12, destiné à être utilisé en traitement pour réduire la taille de la base dilatée du coeur.

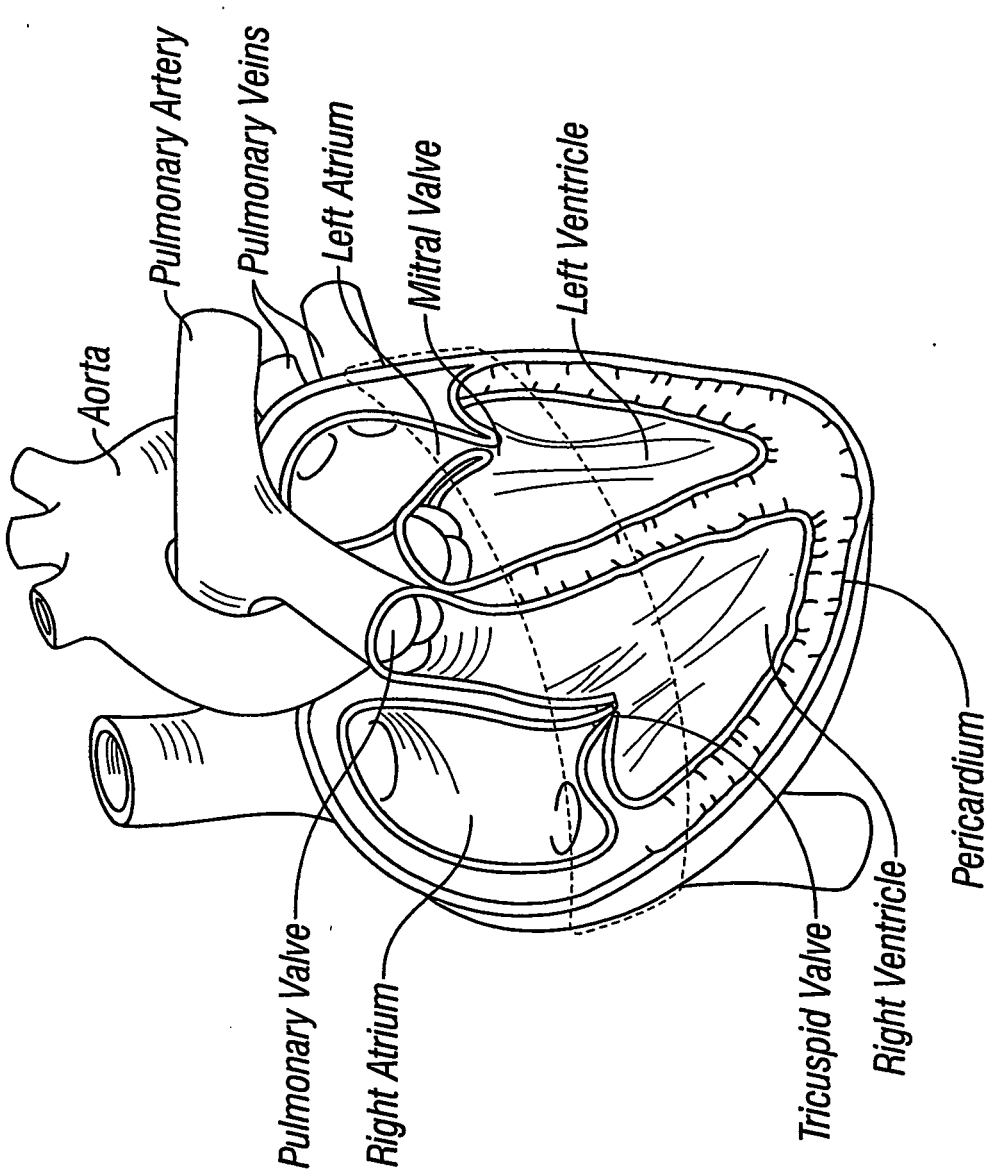
Aorta
Pulmonary Artery
Pulmonary Veins
Left Atrium
Mitral Valve
Left Ventricle
Pulmonary Valve
Right Atrium
Tricuspid Valve
Right Ventricle
Pericardium

FIG. 1

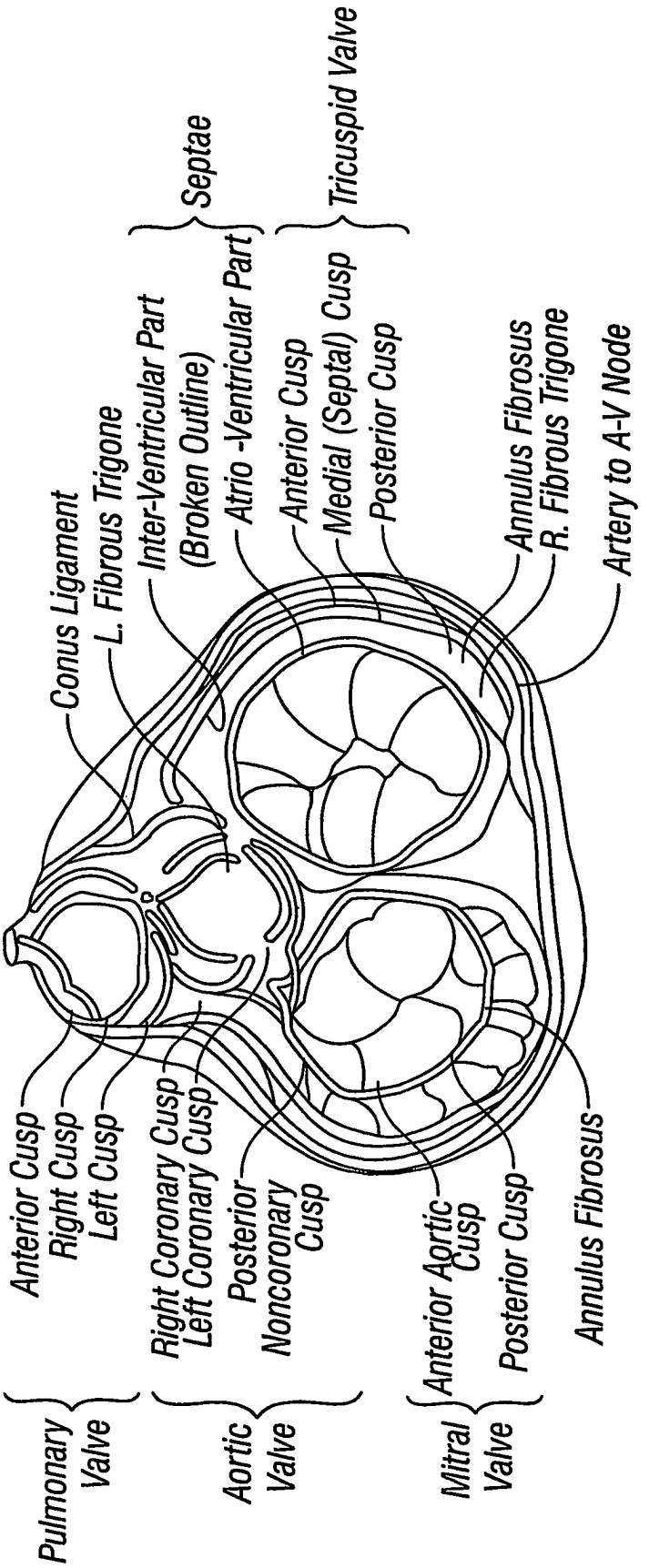
Conus Ligament
L. Fibrous Trigone
Inter-Ventricular Part
(Broken Outline)
Atrio -Ventricular Part
Septae
Anterior Cusp
Medial (Septal) Cusp
Posterior Cusp
Tricuspid Valve
Annulus Fibrosus
R. Fibrous Trigone
Artery to A-V Node
Anterior Cusp
Right Cusp
Left Cusp
Pulmonary Valve
Right Coronary Cusp
Left Coronary Cusp
Posterior Noncoronary Cusp
Aortic Valve
Anterior Aortic Cusp
Posterior Cusp
Mitral Valve
Annulus Fibrosus

FIG. 2

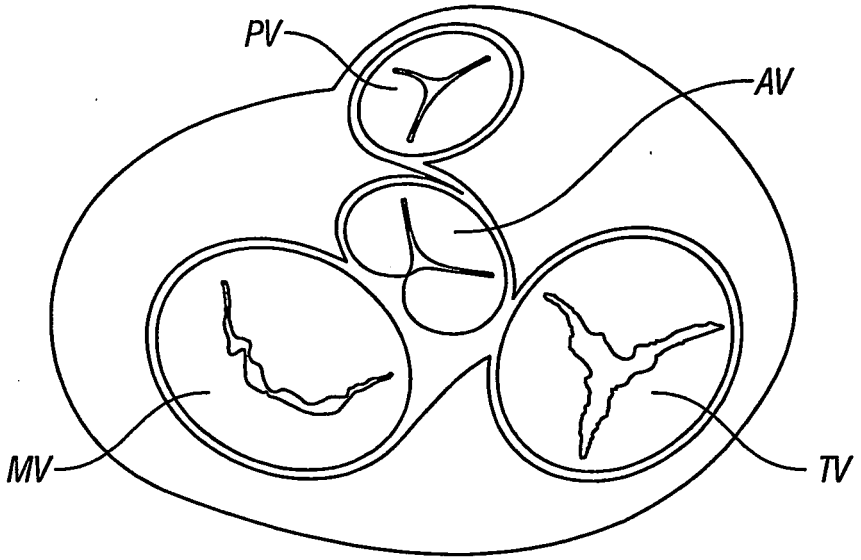

FIG. 3

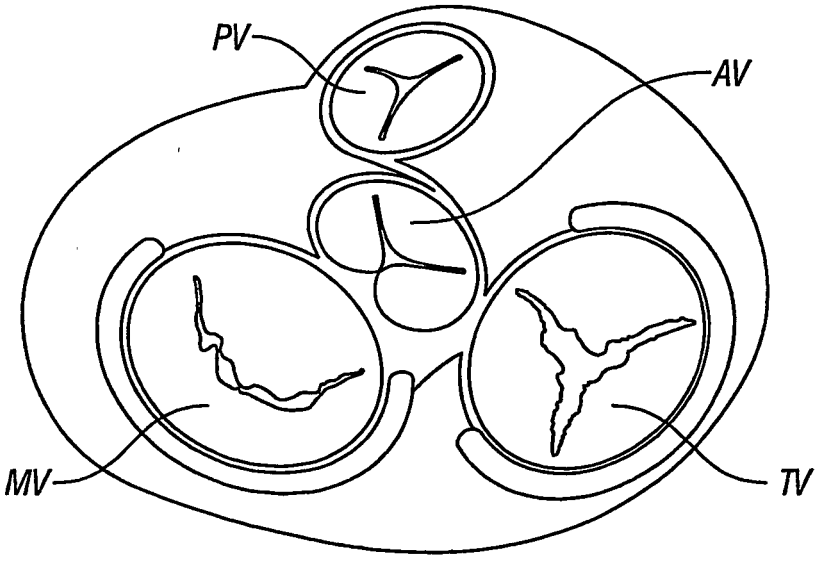

FIG. 4

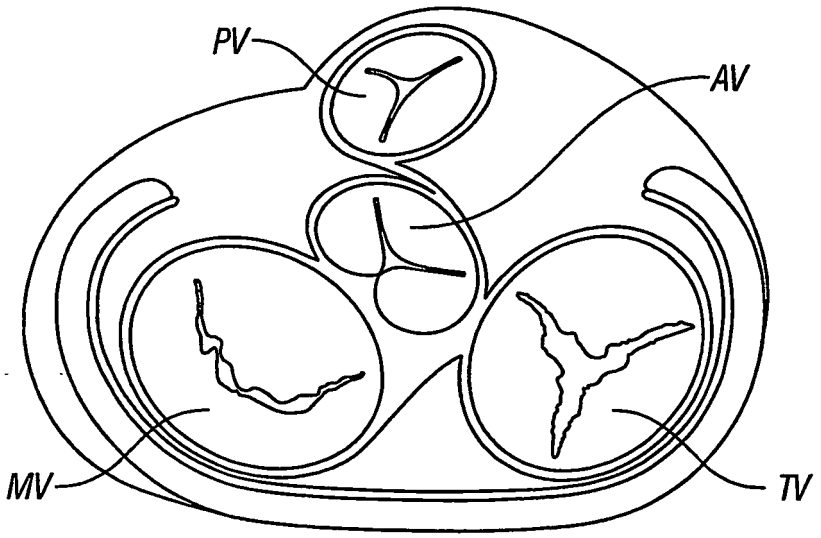

FIG. 5

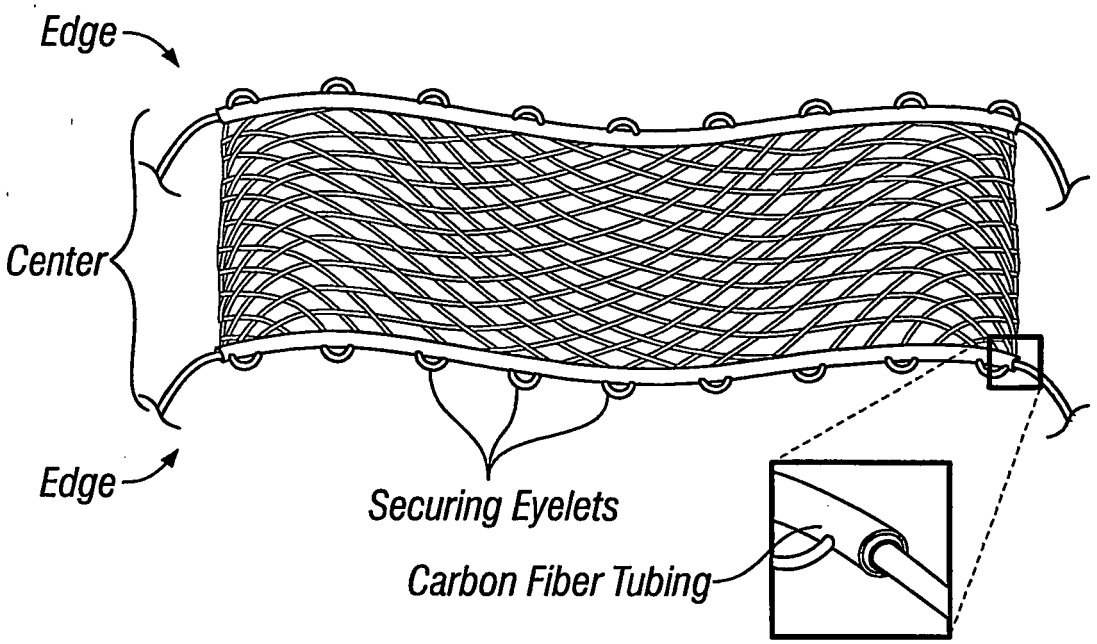

FIG. 6

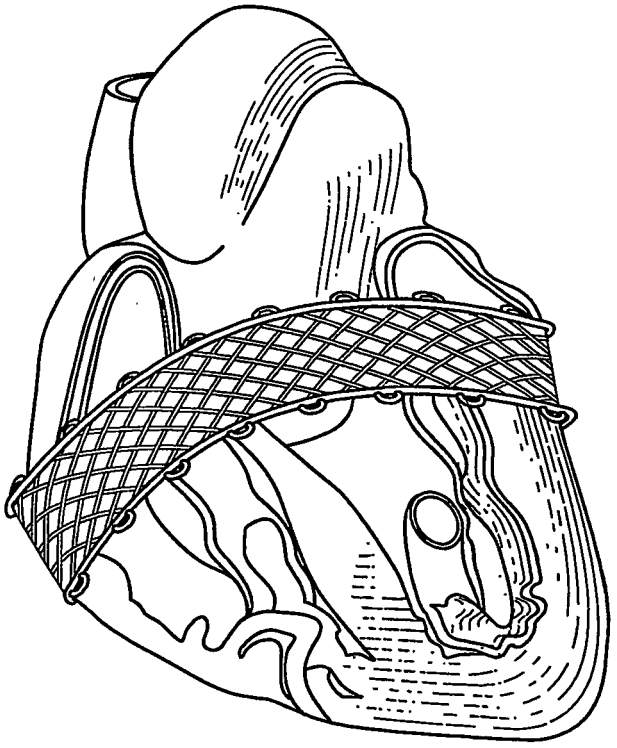

FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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